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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KATAKAM, SUDHAKAR	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
03/16/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,446	UEDA ET AL.	
	Examiner	Art Unit	
	SUDHAKAR KATAKAM	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7 and 10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7 and 10-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the application

1. Receipt of Applicant's Remarks and Arguments filed on 10 Jan 2011 is acknowledged. However, the arguments for the 103(a) rejection are not found persuasive and as such, the previous rejection has been maintained for the reasons of record made on made on 14 Sep 2010.

Response to Arguments

2. Applicant's arguments filed on 10 Jan 2011 have been fully considered but they are not persuasive.

(i) Applicants argue that the office action does not provide the adequate rationale or reasoning as to why persons skilled in the art would wash crystals and/or oil with a water-soluble organic solvent. As already discussed in previous responses, the secondary references do not teach washing crystals.

GB 947643 teaches a preparation and purification of reduced coenzyme Q_{10} from the oxidized form of coenzyme Q_{10} in ethanol and adding excess of sodium borohydride in aqueous medium and the resulted yellow orange compound is diluted with water and the compound is extracted with petroleum ether. The petroleum extracts are washed with water and then dried, which results in crystallized form of reduced coenzyme Q_{10}, the pure hydroquinone of coenzyme Q_{10}. This may be recrystallized from alcohol-petroleum ether mixture. **Kijima et al** (US 4,061,660) teach, in an analogous process, washing of crystals with diethyl ether. **Kijima et al** (US 4,039,573) additionally discloses an analogous washing process where zinc is the catalyst. **Morita et al** (US

4,163,864) also shows an analogous washing process, where methanol is used for washing.

It is clear from the above teachings from the prior art that all the claimed elements were known in the prior art and one skilled person in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

(ii) Applicants argue that the office action cites the secondary references with respect to washing of crystals with water soluble organic solvents. The secondary references do not overcome the above deficiencies of Merck & Co with respect to rendering unpatentable the present invention.

In fact secondary references do teach washing the crystals in their processes. For example, **Kijima et al** (US 4,061,660) teach, in an analogous process, washing of crystals with diethyl ether [see Example 1]. **Kijima et al** (US 4,039,573) additionally discloses an analogous washing process where zinc is the catalyst [see Example 3]. **Morita et al** (US 4,163,864) also shows an analogous washing process, where methanol is used for washing [see Example 1].

(iii) Applicants argue that none of Kijima '600, Kijima '573 and Morita teaches using crystals and/or oil of a desired product to thereby remove a water-soluble impurity.

The secondary references recognized the use of water-soluble solvents, such as methanol and ethanol, for washing crystalline coenzyme Q10, in order to remove the impurities from it. The purpose of washing is to remove the impurities.

(iv) Applicants argue that in the office action, the examiner commented that absent any showing of unusual and/or unexpected results, the art obtains the same effect on the purification of reduced coenzyme Q10. However, since a prima facie case of obviousness has not even been established, comparative experiments or a showing of unexpected results are not actually needed in this application.

The obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it is permissible for the Examiner to rely on disclosures, which fairly teach embodiments of Applicant's invention. The claims require a multitude of elements, such as washing crystals of CoA Q_{10}, and it is reasonable for one of ordinary skill in the art to consider these elements being used together. Applicant is reminded that one can not show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to start with the GB 947643 teachings and combine the teachings of known solvents for the purification process, to achieve the instant claims

with a reasonable expectation success. It is a simple washing to remove impurities using suitable solvents. The selection a solvent is depends on the solubility of the impurities.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-3, 5-7 and 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Merck & Co., Inc** (GB 947,643) and applicants' acknowledged prior art in view of **Kijima et al** (US 4,061,660), **Kijima et al** (US 4,039,573), **Morita et al** (US 4,163,864) and WO 03/006409 & WO 03/006411 (see IDS dated 08/18/2010).

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136 (a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no even, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/
Primary Examiner, Art Unit 1621